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NO. 88-614

IN THE
SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1988

9/1 KG. CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, and SCHUYLER LABORATORIES, INC.,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES
COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF OF: Cliff Skiles, D.V.M.
Robert M. Clack, D.V.M.
1506 West Park
Hereford, TX 79045
217/285-4561

IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

Paul K. Zeman, Jr.
303 South Seventh, P.O. Box 339
Vandalia, IL 62471
(618) 283-3034

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Talbot, Fernandez, & Melendez, List of FDA Approved Animal Drug Products. Information Series 87-1 ISSN 0888-2312, LABORATORY OF Veterinary Medical Informatics, V.A.-MDR Regional College of Veterinary Medicine, Virginia Polytechnic Institute and State University, Blacksburg, Virginia.....25

FDA Import Alert, Bulk New Animal Drug Substances, Regulatory Procedure Manual, Part IX, Imports Chapter 9,-79, ADFS-DFRG (HFO-415), Field Compliance Branch No.:68-09 (Revised), November 4, 1983.....26

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BRIEF OF DR. CLIFF SKILES AND DR. ROBERT M. CLACK IN SUPPORT OF PETITIONERS' PETITION FOR WRIT OF CERTIORARI

Dr. Cliff Skiles is a licensed veterinarian licensed to practice in Texas and California. Dr. Skiles office is located in Hereford, Texas. Dr. Skiles attended Texas A & M University and earned a Bachelors Degree in Veterinary Science in 1966. Dr. Skiles received a Doctor of Veterinary Medicine degree in 1967 from the same school. In 1971

Dr. Skiles received a Degree of Master of Science in Animal Nutrition from Texas Tech. Dr. Skiles practice is predominantly a large animal practice primarily beef cattle and he works with feed lot operations, farmers, and ranchers. The area around Hereford, Texas is frequently spoken of as the "feedlot capital of the world". Dr. Skiles clients have heards of variable size the largest of which is about 50,000 head of cattle. Their businesses like most farming operations are having serious economic difficulties.

Dr. Robert Clack is licensed to practice veterinary medicine in Illinois, Iowa and Colorado. Dr. Clack attended the University of Illinois and earned a Bachelor of Science degree in animal science in 1972. Dr. Clack earned a Bachelors Degree in Veterinary Science in 1974, Doctor of Veterinary

Medicine Degree in 1976 and a Degree of Master of Science in Animal Nutrition in the fall of 1976 at the same school. Dr. Clack's practice is predominantly a large animal practice of swine and beef cattle. The area around Pittsfield, Illinois used to be spoken of as the "pork capital of the world" and today it is still one of the most important centers of this activity in the United States. Dr. Clack's swine client herds vary in size up to 7000 head of swine.

Practicing veterinarians have always had a long standing successful relationship of protecting the public, the animal owner and the animals he treats. Before a veterinarian is admitted in the profession of veterinary medicine he publicly pledges the veterinarians oath. The veterinarian seldomly

swears to use his scientific knowledge and skills for the benefit of society through the:

1) Protection of Animal Health
2) Relief of Animal Suffering
3) Conservation of Livestock Resources
4) Promotion of Public Health
5) Advancement of Medical Knowledge

The veterinarian further swears to practice his profession conscienciously with dignity and in keeping with the principles of veterinary medical ethics.

It is utmost important that a Writ of Certiorari be granted because veterinarians will not only be unable to uphold the oath they have taken and will be unable to do their job if the decision in the Seventh Circuit is allowed to stand.

ISSUE

Whether the Food, Drug, & Cosmetic Act Gives the FDA Authority to Control Veterinarians?

FACTS

Animal drugs can be divided into three (3) distinct categories. The first category is the FDA approved animal drugs. FDA has only approved approximately 1400 animal drugs to treat all the species of animals that exist in America. When we contrast this to human medicine, we find that FDA has approved approximately 50,000 drugs to treat one species. This great discrepancy is due to economics and the misconception that FDA is the one that approves drugs. Alot of people believe that FDA approves drugs to take care of the disease in animals. In reality FDA leaves the drug approving process up the drug companies, and they decide based on

economics whether it is economically feasible for them to approve drugs for a disease in a species of animals.

Unlike the human world, food animal production in the U.S. is based on economics; and if the drug is too costly, the farmer can not use it. This economic fact is well understood by the drug companies, and they will simply not spend the estimated 10 million dollars and 10 years in development it takes to approve a drug unless they can justify a return on their investment. As a result of this economic fact, the drug companies have only approved 1400 drugs for all animals that exist in America. To say the least there are alot of species of animals and alot of disease in animals with no drugs approved for them. In very simplistic terms there is

no way a veterinarian can do his job with only 1400 approved animal drugs to work with.

It is even more alarming when we break the 1400 approved animal drugs down into the ones approved for food animals. FDA has only approved around 700 drugs to treat the food animals with of which only 49 are controlled by the veterinarian. This means that out of the 700 drugs approved for food animals 651 are sold freely over the counter to anyone in the U.S., herein referred to as OTC. This means that FDA is allowing 93% of all the approved food animal drugs to be manufactured and sold directly to livestock producers for use directly in food animals without any veterinarian supervision. What has resulted over the last 30 years of FDA allowing indiscriminate use, over use and

misuse of approved food animal drugs by the livestock producer diagnosing and treating their own animals is infectious diseases have developed resistance to the FDA approved food animal drugs rendering them ineffective for theraputic use in treating disease conditions in food animals.

The second category of animal drugs is FDA's Unapproved Animal Drugs. In the 27th report in 1985 by the Committee on Government Operations CVM officials stated, "FDA has failed to regulate the distribution and use of unapproved new animal drugs. CVM officials believe that as many as 90% or more of the 20,000 to 30,000 new animal drugs estimated to be on the market have not been approved by FDA as safe and effective and, therefore, are being marketed in violation of the new animal drug approval

requirements of the Food, Drug, and Cosmetic Act. It is estimated that as many as 4000 of these new animal drugs may have "potentially significant adverse effects on animals or humans". This means that FDA is allowing drug companies to freely manufacture and sell an estimated 18,000- 27,000 animal drugs that have never been approved. It is even more alarming when one realizes that FDA is allowing all these drugs that have never been approved to be safe and effective to be manufactured and sold freely OTC to anyone without any veterinary supervision.

So we have the federal agency who is charged with assuring that drugs are to be safe and effective before they are freely marketed to protect the public from residue in our meat milk and eggs sanctioning the illegal man-

ufacture and distribution OTC of unapproved animal drugs. The FDA funded by our U.S. tax dollars is allowing drug companies to break the law and endanger the public with residue in our meat, milk and eggs. Again, from the infectious disease standpoint what has happened by FDA allowing these unapproved drugs to flow freely OTC during the last 30 years is infectious diseases have developed resistance to these unapproved drugs rendering them ineffective in most cases.

The third category of animal drugs is veterinarians compounding medicine to be administered and prescribed in the course of their professional private practice. There is no way of knowing how many drugs are represented in this category because these drugs are private prescriptions between the

veterinarian and his client and they will change as the disease condition dictates. This category of drugs are also not approved by the FDA, but this category is legal as all practitioners of the various fields of healing arts are exempt from the FDA approval process.

When Congress passed the 1938 Federal Food Drug & Cosmetics Act at Section 510[360](g)(2), they very wisely exempted all practitioners from registering with the FDA and going through the drug approval process at Section 510[360](g)(2) when, "Practitioners licensed to by law to prescribe and administer drug and devices and who manufacture, prepare, propogate, compound, or process drugs and devices solely for use in the course of their professional practice". Congress very

wisely recognized that the drug approval system they had enacted was very time consuming and costly and would be out of the grasp of health practitioners. They recognized that patients and the diseases that affect them are not static and fixed like the FDA drug approval system so they left flexibility in the system so the members of the healing arts could protect the public and patients.

With years of formal education and state licensure accompanying each member of the healing arts, Congress felt comfortable that the public would be safely protected in granting this exemption to the practitioners of the healing arts.

FACTUAL CONSEQUENCES IF A WRIT OF CERTIORARI IS NOT GRANTED

I. Due to FDA's policies of allowing almost all of the approved animal drugs and all of the unapproved animal drugs to be freely sold OTC over the last 30 years, infectious diseases has developed resistance to these drugs. In contrast, in human medicine 99.6% of all the 50,000 drugs are first of all approved & secondly all drugs and vaccines that are used to treat infectious diseases are under the direct supervision of the physician.

As a result in human medicine you do not have the widespread drug resistance to infectious diseases as you do in animal medicine. So as the result of this widespread drug resistance that has

developed in the animal world, veterinarians more than ever today must purchase the chemicals to compound into medicinse to treat the infectious diseases that are resistant to FDA's approved and unapproved animal drugs. If veterinarians are no longer allowed to purchase chemicals to compound their own effective medicine, then animals will suffer, die and the public health will be put in jeapordy.

II. There are approximately 250 diseases that can spread from animal to man. Veterinarians work directly with the livestock producer are in the best position to stop the disease transfer from animal to man. Many of these diseases have no drugs approved to treat them with and many of these diseases are also resistant to FDA's approved and unapproved animal drugs. If

veterinarians cannot purchase chemicals to compound his own effective medicine to treat these diseases they can spread to man and threaten the public health.

III. Diseased food animals will enter the stream of commerce and threaten public health. With the Seventh Circuit's decision if a farmer has a herd of animals infected with a disease and they are dying because FDA's approved and unapproved drugs are not working and the farmer does not have the option of veterinarians compounding medicine to treat his animals, the livestock producer will sell the infected animals that are in the early stage of infection to slaughter. Most animals in the early stage of infection will pass the ante-mortem inspection at most slaughter facilities resulting in diseased

animals entering the stream of commerce endangering public health.

IV. With widespread practice of "factory farming" the raising of food animals in large masses designed to maximize economy of scale, what has resulted is impaired immunity in farm animals due to increased stress. With immunity lowered the animals defenses are decreased resulting in an animal that is very susceptible to acquiring a disease and the disease spreading throughout the herd. Most of the time the farm has already tried the approved and unapproved animal drugs and they are not working, so the veterinarian has no other option than to compound more powerful drugs or combinations thereof from chemicals to treat the animals. If chemicals are not available for veterinarians to compound the

net result will be loss of livestock resources, animals will die and suffer.

V. FDA and the drug companies have not approved enough drugs to treat the diseases in the species. In the majority of species of animals that exist in America there are very few and in many species of animals there are no drugs approved to treat the diseases at all. Please see the affidavits filed by the veterinarians in this case found in the Supplemental Appendix of Appellees filed in the Seventh Circuit.

VI. The majority of all drugs that FDA and the drug companies are marketing that are approved and unapproved are drugs that are already compounded. In 98% of the cases if the veterinarian can only purchase compounded approved animal drugs from a drug

company he cannot use them to compound his own medicine because the carriers, vehicles and extenders that one drug company uses to compound the approval animal drug in most circumstances are not compatible with the carriers, vehicles and extenders that another company uses to compound their approved animal drug. So FDA knows if they can keep the pure chemicals out of the hands of the veterinarian then they will essentially stop all veterinarians from compounding. If veterinarians cannot purchase pure chemicals to compound medicines; then animal health will be in danger, animals will suffer, we will lose livestock resources, public health will be in danger, and advancement of medical knowledge will almost come to a stop.

VII. FDA and the drug companies have not

approved all drug formulations to be used in all acceptable dosing regiments. As the result if veterinarians cannot purchase pure chemicals to compound medicine the use of valuable drugs would be very limited. For instance FDA and the drug companies have only approved the use of the valuable antibiotic polymyxin for only ophthalmic ointments. If the veterinarian diagnosed a disease that required polymyxin to be injected into an animal, the formulation that FDA and the drug companies have approved are not suitable for such uses. The net result would be if a veterinarian cannot purchase polymyxin as a pure chemical to use in compounding medicine other uses for this valuable drug would not be available to the animal world.

VIII. FDA and the drug companies have <u>not</u>

approved the drugs to be used in all species. For instance the valuable drug cephapirin is the only approved for intramammary infusion in the cow. If a veterinarian wanted to use cephapirin in the pig, dog, cat, sheep, birds, or any other specie it cannot be used under FDA's and the drug company's approval system because they have only approved it for the cow and even more specific only for intramammary infusion in the cow. Again, as noted in Number VII you cannot take a product formulated for intramammary infusion and inject it into an animal. The intramammory formulation is not compatable for injection purposes. As a result if the veterinarian cannot purchase cephapirin as a pure chemical to use in compounding medicine, other valuable uses of this drug would not be available to the animal world.

IX. If the Seventh Circuit's decision is allowed to stand it will have negative consequences to many advances in human medicine and knowledge. Many advances in human medicine are gained from the knowledge of clinical studies on sick animals. Human diseases such as cancer and immune-deficiency extensively use animals in their research to help discover a cure for these diseases.

X. In just the last 10 years we have seen the following new diseases develop in swine industry which are:

Strepptococcus Suis Type II
Leptospira Brataslava
Haemophilus Parahemaliticus
Haemophilus Suis

Clostridium Type C
Coccidiosis

Strepptococcus Suis Type II has killed several slaughter plant workers when it first developed into a disease. We hate to think what would have been the outcome to the public and the animal world if veterinarians could not compound medications to treat these diseases. This is not an uncommon occurrence. As you can see from the new diseases that have developed in swine in just the last 10 years. If veterinarians do not have the tools available to work quickly the results will be disasterous.

If the veterinarian had waited the 10 year average for FDA and the drug companies to approve drugs for these diseases; the loss

would have been disasterous for the farmer, the suffering animal, and the public health. Who knows what new disease will develop in the future? If we put complete control in the hands of the FDA, we could lose species of animals and likewise the threat to humans would be great. What FDA is proposing is that the educated and trained veterinarian wait for FDA and a drug company to approve a specific drug formulation for each specific species of animal and disease condition even though the veterinarian has been educated and trained to effectively treat the disease and even though the chemicals are already approved and being used by the drug companies in the U.S.

We are not talking about the veterinarians purchasing chemicals that have never been approved for use in this country or chem-

icals that have been banned for use in food animals. We are talking about veterinarians purchasing the active drug ingredient in pure form of drugs FDA already have approved and for the veterinarian to use their chemicals in compounding medication for the protection of the public, the livestock industry and the animals that exist in America because FDA has not done their job.

THE LAW

Section 360 is the registration of producers of drugs and devices of the Federal Food, Drug & Cosmetic Act. At (g) in this Section Congress specifically enacted that "the foregoing subsection of this section shall not apply to-

> (2) Practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propogate,

compound, or process drugs and devices solely for use in the course of their professional practice.

(3) Persons who manufacture, prepare, propogate, compound or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale.

Enclosed is the catalog from Sigma Chemical Company. This catalog contains over 21,000 chemicals. In the 1987 List of FDA Approved Animal Drug Products by Richard B. Talbot of Virginia Polytehnic Institute & State University, Section 5 is a list of FDA's Selected Active Ingredients of the Approved Animal Drug Products. There are 291 Selected Active Approved Animal Drug Ingredients and

over 50% of these drug ingredients can be found in the Sigma catalog. In the FDA Regulatory Procedure Manual, Part 9 is FDA's 1983 Import Alert Policy entitled Bulk New Animal Drug Substances, FDA lists 50 New Animal Drugs and 86% of these New Animal Drugs can be found in the Sigma catalog. The Sigma catalog also contains a vast number of the chemicals used in the U.S. plus toxic chemicals, chemicals that are known cancer producing agents, and controlled substances.

The question is are these chemicals drugs when a veterinarian purchases them. The answer to this question can be found in Section 201. The definition section of the Federal Food, Drug & Cosmetic Act defines the term "drug". This section defines the term "drug" at (B) as "articles intended for use in the diagnosis, cure, mitigation, treat

ment, or prevention of disease in man or other animals."

When a doctor purchases a chemical no one knows if he intends to use that chemical on or in an animal. Only when the doctor compounds or formulates the chemical and prescribes or administers it in or to be used in or on an animal or man is anyone certain that the doctor intends to use the chemical as a drug. Again as we refer back to Section 510[360](g)(2) we find that Practitioners of the fields of healing arts do not have to register with the FDA as producers of drugs and devices and go through FDA's new animal drug approval process. If the Seventh Circuit decision is allowed to stand, FDA will have the law defined to say that all chemicals are new animal drugs and before a doctor can purchase a checmical which is a

"new animal drug" he must first get it approved if he is a member of the field of healing arts.

If the Seventh Circuit is not reversed, all chemicals purchased in the enclosed Sigma Chemical Catalog or any other company such as common limestone (calcium carbonate) on Page 361 and table sugar (sucrose) on Page 1302 will have to be approved by the FDA before a veterinarian can purchase them. Even if a veterinarian intended to prescribe or administer these chemicals in animal feed, as a nutritional additive, FDA could stop the purchase by a veterinarian because FDA would have all chemicals defined as "new animal drugs" when purchased by members of the healing arts. The animal industry and the human world consider both limestone and sugar to be normal requirements or additives of the

every day diet of animals and humans, but FDA would have the law to state otherwise if the Seventh Circuit decision is not overturned.

The real irony of the whole situation is that FDA recognizes that teachers, chemists and other laymen are exempt at Section 510[360](g)(3) from registering as producers of drugs and devices and freely allows them to purchase all the chemicals in the Sigma Catalog even the products that FDA claims as drugs even the products FDA claims as "new animal drugs", but when it comes to veterinarians FDA says they do not fall in this exemption at Section 510[360](g)(2) and veterinarians have to approve everything the veterinarian prescribes or administers.

FDA is very inconsistent in interpreting the law as it applies to veterinarians and FDA is

discriminating against veterinarians. If the Seventh Circuit decision is allowed to stand, it will not be the animal drug industry that is turned upside down as FDA claims but it will be the veterinarian medical profession and the animal industry that it turned upside down. As complete control of prescribing and administering drugs will be placed in the hands of FDA and the drug companies approval system. The veterinarian will be separated from the animal owner, the public will suffer and the animal industry will suffer. In essence, the few benefits that such a restrictive regulatory policy would have is far outweighed by the harm that such a policy would have on animal industry and the public.

Veterinarians Need to Purchase and Use Chemicals, Not as Drugs to Treat Animals, In Order to Do Their Job FDA's assumption is that whenever a veterinarian purchases chemicals he intends to use these chemicals as a drug in treating animals. Dr. Gerald Guest of the FDA in deposition could not think of any chemical that was not a new animal drug. Supplemental Appendix of Appellees filed with Seventh Circuit at Page 45. Dr. Andrew Beaulieu of the FDA in deposition could only think of two (2) drugs that were not new animal drugs which were sodium chloride (common table salt) and epsom salt. Appellant Appendix in the Seventh Circuit at Page 21. Since FDA's position is that essentially all chemicals are new animal drugs the veterinarian will have to approve all chemicals he purchases except sodium chloride and epsom salt. If the Seventh

Circuit decision stands, FDA will be bound by law to stop all chemical purchases by a veterinarian except perhaps the purchase of sodium chloride & epsom salt. Veterinarians cannot do their job without pure chemicals. Examples follow:

1. The veterinarian today is a multi-faceted individual that is involved in every area of animal rearing. Nutritional recommendations, prescribing and administration are common place to most veterinary practices. Alot of the daily recommended nutritional requirements are chemicals such as minerals, true minerals and vitamins. If the Seventh Circuit decision stands the veterinarian would not be allowed by law to purchase the nutritional chemicals whereas any

non-veterinarian could freely purchase and recommend usage of these chemicals.

2. Many of veterinarians are involved in semen collection and insemination. After the semen is collected from an animal, it is mixed with extenders that prolong its life outside the animals body and facilicate the fertilization process once it is inseminated into the female animal. The extenders are made from chemicals. Pure chemicals or drugs have to be used in the extenders for if an approved drug is used the vehicles, carriers and extenders that are used by the drug company in compounding the approval drug will kill the semen. If the Seventh Circuit decision is allowed to stand, non-veterinarians will be allowed to purchase and use such

chemicals but by law veterinarians will not.

3. A large number of veterinarians have their own diagnostic laboratory, bacteriology laboratory, nutritional laboratory, and etc. These laboratories cannot function without the use of chemicals and they require different chemicals to function. For instance some veterinarians choose to make their own antibiotic sensitivity disc. In order to do this the veterinarian must buy pure drugs or chemicals free of extenders, carriers, and vehicles. If the Seventh Circuit decision stands, veterinarians by law would not be able to purchase these chemicals but non-veterinarians could do so.

4. Veterinarians use alot of chemicals in there every day routine practice, but not as drugs in treating disease conditions. Some such uses would be disinfectants, cleaning agents, antiseptic agents, and regents. If a veterinarian uses a chemical that is traditionally thought of as a drug, as a disinfectant is it a drug or a chemical? If the Seventh Circuit decision is allowed to stand, FDA by law will recognize it as a new animal drug and stop the veterinarian from purchasing the chemical. Again non-veterinarians would be allowed to purchase the chemicals.

CONCLUSION

If FDA is allowed to control the chemicals and the compounding of medicines by the licensed veterinarian, then the results will

be veterinary medicine controlled by the FDA and the drug companies. This would result in a profession that will be reduced to trained professionals reading labels and counting pill doses to his clients. This would result in the loss of the art of medicine, clinical knowledge and advancement of veterinary medicine. This will result in the animal owner purchasing the same drugs as the veterinarian, reading the same labels, and counting the same pills and doses. This will result in the separation of the veterinarian from the animal owner. (There will be no need for licensed veterinarians if the animal owner can purchase and administer essentially everything that a veterinarian can). This will result in decreased protection of animal health, increased suffering in animals, decreased conservation of livestock resources, decreased promotion of public

health and decreased advancement of medical knowledge. The harm of such a policy have be devestating to the animal world, our food supply and public health. For all the reasons set forth in the Brief of Petitioner Schuyler Laboratories, Inc. this Court should exercise its discretion to review the decision reached by the Seventh Circuit Court of Appeals.

Respectfully submitted,

/s/Cliff Skiles, D.V.M.

/s/Robert M. Clack, D.V.M.

1506 West Park
Hereford, TX 79045